K090663
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7.3 510(k) Summary Statement (21CFR 807.92)

Submitter	American Medical Systems Inc. (AMS) 10700 Bren Road West Minnetonka, MN 55343
Contact Person	Stephanie George Phone (952)-930-6389 Fax (952)-930-5785 Paul Bulger Phone (952) 930-6543 Fax (952) 930-5785
Preparation Date	March 10, 2009
Device Common Name	Penile Prosthesis
Device Trade Name	AMS Spectra™ Concealable Penile Prosthesis
CFR Number	21 CFR Part 876.3630
Regulatory Class	Class II (special controls)
Product Codes	78 FAE (penile prosthesis)
Predicate Devices	AMS Spectra™ Concealable Penile Prosthesis (K082006) AMS DURA II® Penile Prosthesis (K953640)

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Indications for Use

The AMS Spectra™ Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery.

Device Description

The AMS Spectra™ Concealable Penile Prosthesis consists of a pair of cylinders which are surgically implanted, one into each corpus cavernosum, to provide penile rigidity. Each device consists of two cylinders and may include rear tip extenders (RTEs) for additional length. All components consist of implantable, biocompatible materials.

The cylinder consists of a malleable section of articulating polymer and metal segments. A cable extends through the center of the articulating segments. The

proximal and distal ends of the cable are each connected to a spring that is encased in a metal housing. The entire outside surface of the cylinder is made of silicone.

The articulating segments, held together by the cable and spring assemblies, provide sufficient friction and rigidity. This allows the patient to position the device for concealment or for intercourse.

Spectra cylinders are available in 9.5-, 12-, and 14-mm diameters. Each cylinder diameter is available in three lengths: 12-, 16-, and 20-cm.

The total cylinder length can be adjusted by adding rear tip extenders (RTEs) to the proximal cylinder end. A range of RTE lengths is included to accommodate the patient's total intracorporal length.

Rear tip extenders may be attached to the Spectra™ cylinders in 0.5-cm increments, and may extend the cylinder lengths from 0.5- to 7.5-cm, with the exception of 7-cm. The RTEs are the same as those used with the inflatable AMS 700™ CXR and CX/LGX models (D970012). These RTE components' functional performance has been demonstrated in use with the 700™ IPP products.

Substantial Equivalence

The AMS Spectra™ Concealable Penile Prosthesis was subjected to mechanical performance tests to evaluate its function. These tests included evaluations of cycle life, springback angle, column strength (rigidity), bend force, and packaging. For each test, acceptance criteria were established prior to testing. The outcome of each test was that the acceptance criteria were met by the Spectra™ product, demonstrating substantial equivalence to the predicate products.

Because the intended use and technological characteristics of the predicate Spectra™ and DURA II® devices were maintained in the subject AMS Spectra™, a clinical study was not conducted for the subject Spectra™ device.

The nonclinical performance tests demonstrated that the Spectra™ device is as safe, as effective, and performs as well as or better than the predicate Spectra™ and DURA II® penile prostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Stephanie George
Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
MINNETONKA MN 55343

APR - 9 2009

Re: K090663
Trade/Device Name: AMS Spectra™ Concealable Penile Prosthesis
Regulation Number: 21 CFR 876.3630
Regulation Name: Penile rigidity implant
Regulatory Class: II
Product Code: FAE
Dated: March 10, 2009
Received: March 12, 2009

Dear Ms. George:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

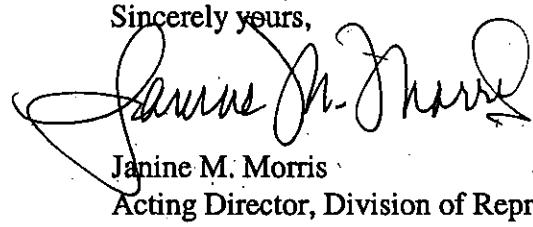
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7.2 Statement of Indications for Use

Indications for Use

510(k) Number (if known): K090663 ~~Unknown~~

Device Names: AMS Spectra™ Concealable Penile Prosthesis

Indications For Use: The AMS Spectra™ Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090663